AMENDMENT TO THE SPECIFICATION

Applicants amend the specification in pursuant to 37 C.F.R. 1.57(g)(2) MPEP 608.01(p), which states in part the following:

"....to replace the original incorporation by reference with the intended incorporation by reference. A citation of a patent application by attorney docket number, inventor name, filing date and title of invention may sufficiently describe the document, but even then correction should be made to specify the application number."

Please amend the following paragraphs:

[0001] The subject matter of this application relates to the patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534 ~~Attorney Docket No. IVQ-001~~, and filed on even date herewith.

[0044] FIG. 2 provides a functional layout of an embodiment of the present invention. Protocol development 200 involves a review of the goals of the clinical trial to determine research protocol including subject compliance targets prior to the start of the clinical trial. Preferably, compliance targets are developed in accordance with the invention disclosed in the co-pending patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534~~Attorney Docket No. IVQ-001~~.

[0046] It is also within the scope of the present invention to use empirically derived algorithms to determine the best compliance targets for a specific clinical trial by the use of the quantitative analysis methods of the patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. 09/825,534~~Attorney Docket No. IVQ-001~~.

[0050] Moreover, portable electronic devices can optionally track all aspects of their use, resulting in a comprehensive record of subject compliance with the research protocol. A preferred embodiment of the invention allows clinical trial staff to systematically collect data regarding subject compliance by tracking a variety of different components of compliance, as well as check in compliance against empirically derived algorithms and decision rules of compliance. These empirically derived algorithms and decision rules allow the disclosed invention to examine the data for nonintuitive and complex combinations of predictors to proactively determine whether the observed pattern of interaction with the portable electronic device suggests noncompliance. The patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534 ~~Attorney Docket No. IVQ-001~~ provides additional detail regarding such algorithms and decision rules.

[0052] Compliance feature design 300 includes standard features 310, trial specific features 320, and evaluability needs 330. Incorporating standard features 310 within the research protocol preferably involves review of historic data from previous research 340, including prior operations of the invention on earlier clinical trials and other sources of data involving subject compliance and, preferably, associated research protocols. Preferably, standard features 310 incorporated into the protocol will be derived in accordance with co-pending patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534 ~~Attorney Docket No. IVQ-001~~, and will involve historic data from related clinical trials. For example, a clinical trial related to a cardiovascular condition will preferably develop standard compliance features 310 from historic data involving cardiovascular clinical trials.

[0057] During and/or after trial execution 400, compliance tracking 500 is performed and involves analyzing subject behavior data and comparing it to the research protocol. Compliance tracking data, e.g. evaluability data, is gathered during the clinical trial and compared to historic norms 510 during or after the clinical by the use of decision rules. Additional detail is provided in the patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534 ~~Attorney Docket No. IVQ-001~~.

[0095] Additional detail regarding the method illustrated in FIG. 5 is provided in the patent application titled "Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research", U.S. Pat. Application No. No. 09/825,534 ~~Attorney Docket No. IVQ-001~~.